

REMARKS

Claims 2-5 and 7, and 9-34 are pending in the application. Claims 9, 16, 17, and 26 are independent claims.

Claims 2-5, 7 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The rejection proffers that the language "such that the detection element is downstream of the cover" does not exclude the cover from also being upstream.

Claim 9 is amended to recite that the detection element is positioned downstream of the first and second outer edges of the cover. Support for the amendment is found in the specification and drawings and particularly at Figs 1A-1D and 1G. No new matter is added by virtue of the amendment.

In light of the above, the claim 9 is believed to be sufficiently definite in accordance with 35 U.S.C. 112, second paragraph. Claims 2-5, 7 and 10-14 depend from independent claim 9. Reconsideration of the rejection, leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 2-5, 7, and 9-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6, 592,815. The rejection is respectfully traversed. It is respectfully submitted that the two sets of claims do not read on each other. However, if the rejection is maintained, a terminal disclaimer will be submitted upon receipt of a Notice of Allowance for this matter.

Claims 4-5, 9-14, 16-18, 21-22, 24-27, 30-31, and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,843,691 to Douglas et al. or U.S. Pat. No. 5,814,522 to Zimmer et al. The rejection is traversed at least for the reasons set forth below.

Before discussing the specifics of the rejection, the Examiner's statement on page 4, last paragraph the Office Action that "Applicant's state the instant claims are directed to a sample hole (30) the [sic.] is spaced from an end of the bottom layer (26)" is respectfully traversed. The Examiner's attention is directed to page 8, first full

paragraph of the Reply filed on April 14, 2005, where it states, "The Examiner's attention is directed to . . . Figure 2 of Douglas et al. . . . *In contrast to the amended claims*, the sample hole (30) shown in Figure 2 is spaced apart from an end of the bottom layer (26)." (*Emphasis added*). As such, the undersigned was contrasting the pending claims with Douglas et al. and in no way was limiting the pending claims to the structures recited by Douglas et al.

It is submitted that Douglas et al. fails to disclose or suggest the device as recited by amended claims 9, 16, 17, and 26.

Claims 9, 16, and 17 are each amended to recite a cover having "a cover having a surface defined by opposite first and second outer edges extending away from the surface, the surface facing the carrier and the second outer edge facing the first end of the detection element". The claims are further amended to recite that the detection element is "downstream of the opposite first and second outer edges of the cover". Support for the amendment is found in the specification and drawings and particularly at Figs 1A-1D and 1G. No new matter is added by virtue of the amendment.

1. Douglas et al. fail to disclose or suggest a surface of a cover facing a carrier and a second outer edge of the cover extending away from the surface of the cover and facing the first end of the detection element, as recited by claims 9, 16 and 17. The rejection proffers that Douglas et al. disclose first and second covers (24, 36). (Page 3, paragraph 4 of the Office Action mailed 6/23/04). The Examiner's attention is directed to Figure 4 of Douglas et al., which teaches that neither the intermediate layer (24), nor the top layer (36) of the matrix (10) has an outer edge that faces a detection element. An examination of Figure 4 of Douglas et al. reveals just the opposite, the outer edges of the intermediate and top layers (24, 36), face away from the assay area (3). As such, Douglas et al. fail to disclose or suggest a surface of a cover facing a carrier and a second outer edge of the cover extending away from the surface of the cover and facing the first end of the detection element, as recited by claims 9, 16 and 17.

2. Douglas et al. fail to disclose or suggest a channel having a sample application opening defined by at least one border positioned at one of the carrier

ends, as recited by claims 9, 16, 17, and 26. The rejection proffers that Douglas et al. discloses a carrier (26). (Page 3, paragraph 4 of the Office Action mailed 6/23/04). Douglas et al. teach at Column 12 lines 47-48 that the "sample is introduced through sample hole 30". Figure 2 of Douglas et al. illustrates that this sample hole (30) is formed in the top layer (36), spaced apart from the ends of both the top layer (36) and the ends of the bottom layer (26). Accordingly, Douglas et al. fail to disclose or suggest a channel having a sample application opening defined by at least one border positioned at one of the carrier ends, as recited by claims 9, 16, 17, and 26.

3. Douglas et al. fail to disclose or suggest a detection element that is downstream of the opposite first and second outer edges of the cover. The rejection proffers that Douglas et al. teach a cover that extends both upstream and downstream from [sic.] the detection element and that Douglas et al. discloses first and second covers (24, 36). (Page 3, paragraph 5 of the Office Action mailed /27/05 and page 3 paragraph 4 of the Office Action mailed 6/23/04).

- a. The Examiner's attention is directed first to the bottom layer (26) of Douglas et al. Figure 2 of Douglas et al. illustrates that the bottom layer (26) has opposite ends and edges that extend between those ends. Column 12 lines 47-51 as well as Figure 2 of Douglas et al. teaches that "sample is introduced through sample hole 30 and is directed by capillary action along central channel 32 of intermediate layer 24 to each of the assay area and the timing area, any excess sample being absorbed in absorbent layers 20 and 22". As such, both ends of the bottom layer (26) of Douglas et al. are downstream of the assay and timing areas. In addition, Figure 3 of Douglas et al. illustrates that the edges of the bottom layer (26) that extend between the ends lie outside of the capillary channel (32), making them neither upstream nor downstream of the array and timing areas. As such, Douglas et al. fails to disclose or suggest "a detection element that is downstream of the opposite first and second outer edges of the cover", as recited by claims 9, 16, and 17.
- b. The Examiner's attention is now directed to the intermediate layer (24) of Douglas et al. Figures 2 and Column 12 lines 30-36 of Douglas et al.

teach that the intermediate layer (24) overlays the membrane (10) and the absorbent layers (20, 22), which are located at the ends of the membrane (10). Column 12 lines 47-51 as well as Figure 2 of Douglas et al. teach that "sample is introduced through sample hole 30 and is directed by capillary action along central channel 32 of intermediate layer 24 to each of the assay area and the timing area, any excess sample being absorbed in absorbent layers 20 and 22". As such, both ends of the intermediate layer (24) of Douglas et al. are downstream assay and timing areas. In addition, Figure 4 of Douglas et al. illustrates that the edges of the intermediate layer (24) that extend between its ends lie outside of the capillary channel (32) making them neither upstream nor downstream of the array and timing areas. As such, Douglas et al. fails to disclose or suggest "a detection element that is downstream of the opposite first and second outer edges of the cover", as recited by claims 9, 16, and 17.

Therefore, Douglas et al. fail to disclose or suggest a detection element that is downstream of the opposite first and second outer edges of the cover.

1. Zimmer et al. fail to disclose or suggest a surface of a cover facing a carrier and a second outer edge of the cover extending away from the surface of the cover and facing the first end of the detection element, as recited by claims 9, 16 and 17. The rejection proffers that Zimmer et al. disclose a cover (8). The Examiner's attention is directed to Figures 3 and 4 of Zimmer et al., which teach that none of the outer edges of the support foil (8) face a detection element. An examination of Figure 4 of Douglas et al. reveals just the opposite, the as the one surface of the foil (8) faces the gap (11) and the outer edges of the support foil (8), which extend away from that surface face away from the test zones (6, 7). As such, Zimmer et al. fail to disclose or suggest a surface of a cover facing a carrier and a second outer edge of the cover extending away from the surface of the cover and facing the first end of the detection element, as recited by claims 9, 16 and 17.

2. Zimmer et al. fail to disclose or suggest at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one border of the sample application opening of the channel, as recited by claims

9, 16, 17, and 26. The rejection proffers that the gap (11) of Zimmer et al. has been read on the claimed notch. It is respectfully submitted that the gap (11) of Zimmer et al. lacks a notch as defined by the pending claims. Specifically, Zimmer et al. teach at Column 8 lines 37-40 "A covering foil (9) is attached with a spacer (10) on the fleece side in such a way that there is a capillary gap (11) in the sample application zone". Figure 4 teaches that the gap (11) is formed between the fleece (1) and the support foil (8). In each illustration, the gap (11) of Zimmer et al. is the channel, and as such, cannot be said to have a width less than the channel's width, as required by the pending claims.

3. Zimmer et al. fail to disclose or suggest a detection element that is downstream of the opposite first and second outer edges of the cover, as recited by claims 9, 16 and 17. The rejection proffers that Zimmer et al. teach a cover (8) this [sic.] is downstream from the reagent (6). The proffer is respectfully traversed.

The Examiner's attention is directed the support foil (8) of Zimmer et al. Figures 3-4 of Zimmer et al. each illustrate that the support foil (8) has opposite ends. Column 8 lines 48-52 teaches that "if the capillary gap (11) is contacted with sample liquid, liquid rapidly fills the entire capillary gap (11). . . Liquid passes from the capillary gap (11) into the sample application zone of the fleece (1)". As such, one end of the support foil (8) is upstream and one end is downstream of the reagents (6, 7). Therefore, Douglas et al. fails to disclose or suggest "a detection element that is downstream of the opposite first and second outer edges of the cover", as recited by claims 9, 16, and 17.

In light of the above, it is respectfully submitted that Douglas et al. and Zimmer et al. each fail to disclose or suggest a device comprising "a carrier having a carrier surface defined by opposite carrier ends, a detection element having opposite first and second ends, and a cover having a surface defined by opposite first and second outer edges extending away from the surface, the surface facing the carrier and the second outer edge facing the first end of the detection element, the cover cooperating with the carrier surface and with the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends, the channel extending at least from the opening to the

second end of the detection element, such that the detection element is downstream of the opposite first and second outer edges of the cover and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 9.

Further, there is no disclosure or suggestion in Douglas et al. and Zimmer et al. of a method for withdrawing a liquid sample into an analytical element, the method comprising the steps of "providing a device that comprises a carrier having a carrier surface defined by opposite carrier ends, a detection element having opposite first and second ends, and a cover having a surface defined by opposite first and second outer edges extending away from the surface, the surface facing the carrier and the second outer edge facing the first end of the detection element, the cover cooperating with the carrier surface and the detection element to form a capillary-active channel having a sample application opening defined by at least one border positioned at one of the carrier ends, the channel extending at least from the opening to the second end of the detection element such that the detection element is downstream of the opposite first and second outer edges of the cover, and wherein at least one notch in the form of a partial groove and having a width less than that of the channel is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface opposite to the at least one notch facing the channel is exposed and contacting the border of the sample application opening adjacent to the notch with the liquid sample so that the liquid sample is transported by capillary forces into the channel", as recited by amended claim 16.

Still further, Douglas et al. and Zimmer et al. do not disclose or suggest a device comprising "a carrier having a carrier surface defined by opposite carrier ends, a detection element having a reagent-impregnated membrane with opposite first and second ends, and a cover having a surface defined by opposite first and second outer edges, extending away from the surface, the surface facing the carrier and the second outer edge facing the first end of the detection element, and the cover cooperating

with the carrier surface and the detection element to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends and extending at least from the opening to the second end of the membrane, such that the detection element is downstream of the opposite first and second outer edges of the cover, and wherein at least one notch in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by amended claim 17.

Still further, there is no description or suggestion in Douglas et al. and Zimmer et al. of a device comprising "a carrier having a carrier surface defined by opposite carrier ends, and a cover having a surface that faces the carrier and that cooperates with the carrier surface to form a capillary-active channel, the channel having a sample application opening defined by at least one border positioned at one of the carrier ends and wherein at least one notch in the form of a partial groove and having a width less than the channel's width is positioned at the at least one border of the sample application opening of the channel so that one side of the border of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed", as recited by claim 26.

As such, claims 9, 16, and 17 as amended and claim 26 are not anticipated and are believed to be patentable over Douglas et al. and Zimmer et al. Claims 4, 5, and 10-14 depend from amended claim 9. Claims 18, 21, 22, and 24-25 depend from amended claim 17. Claims 27, 30-31, and 3-34 depend from claim 26.

It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 102(b). Entry of the amendments leading to reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

Claims 2, 3, 19, 20, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. or Zimmer (USP 5,814,522) either in view of Columbus, Hodges or Lija.

Douglas et al. and Zimmer have been discussed above with reference to independent claims 9, 17, and 26. Claims 2-3 depend from claim 9, claims 19-20 depend from claim 17, and claims 28-29 depend from claim 26.

Columbus et al. (USP 4439526) disclose a device having an exterior surface for receipt of liquid deposited and a wall means interior of the surface for transporting liquid by capillary attraction along a passage. See, Column 2, lines 29-33.

Hodges et al. (USP 5942102) disclose a cell having cylindrical side wall (10) and closed each end by palladium metal. The assembly is notched at (9) to provide for a solution to be admitted to the cell or to be drawn in by wicking or capillary action and to allow air to escape. See Column 5, lines 2-6.

Lija (EP 0138152) discloses a disposable cuvette for sampling a fluid and analyzing the sample. The cuvette includes a body wall (10) that defines a cavities (25, 25') and a channel (26) that directly ends at its edge. See Figure 5.

It is respectfully submitted that the secondary references Columbus et al., Hodges et al., or Lija fail to cure the above-stated inadequacies of Douglas et al. and/or Zimmer et al. in relation to independent claims 9, 17, and 26.

It is respectfully submitted that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

Claims 7, 15, 23, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. or Zimmer (USP 5,814,522) either in view of Hodges and together further in view of Heller.

Douglas et al. and Zimmer et al. have been discussed above with reference to independent claims 9, 17 and 26. Claims 7 and 15 depend from claim 9, claim 23 depends from claim 17 and claim 32 depends from claim 26.

As discussed above, Hodges et al. (USP 5942102) disclose a cell having cylindrical side wall (10) and closed each end by palladium metal. The assembly is notched at (9) to provide for a solution to be admitted to the cell or to be drawn in by wicking or capillary action and to allow air to escape. See Column 5, lines 2-6.

Heller et al. (6238624) disclose a self-addressable, self-assembling microelectronic device designed and fabricated to actively carry out and control multi-step and multiplex molecular biological reactions in microscopic formats. See the abstract.

It is respectfully submitted that the secondary references Hodges et al. and Heller et al. either alone or taken together fail to cure the above-stated inadequacies of Douglas et al. and/or Zimmer et al. in relation to independent claims 9, 17, and 26.

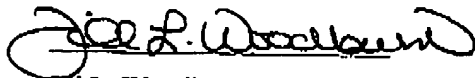
It is respectfully submitted that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

This application is deemed to be in condition for allowance and as such is respectfully requested. In addition, if necessary, it is requested that this paper be considered as a

Petition for an Extension of Time sufficient to effect a timely response and fees be charged to Deposit Account No. 50-0877 (with reference to WP 18622 US).

Respectfully submitted,

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Jill L. Woodburn, Reg. No. 39,874
The Law Office of Jill L. Woodburn, L.L.C.
128 Shore Dr.
Ogden Dunes, IN 46368-1015
Telephone No.: 219-764-4005
Facsimile No.: 219-764-4070